

overcome the rejection and to simplify the issues on appeal. The statutory filing fee under 37 C.F.R. § 1.20(d) is being paid by charge to a deposit account per instructions in the accompanying Transmittal Letter. Since the double patenting rejection is rendered moot by the terminal disclaimer, Applicants respectfully ask that the rejection be withdrawn.

The final Office action has raised one new rejection of the pending claims in that the Examiner now rejects the claims for allegedly containing new matter under 35 U.S.C. § 112, first paragraph, as set forth on pages 4 and 5 of the Office action. Applicants respectfully traverse the rejection for the following reasons.

A new matter rejection is geared towards preventing an applicant from introducing a totally different invention into his/her application where the new matter involves a departure from the original disclosure of the invention. This does not mean that amendments to the claims need to find verbatim support in the specification. In fact, it has never been the Office practice to require that the support for amendments in the specification need to be taken literally, word for word. See, for example, the guidelines in M.P.E.P. § 2163.07 that state that rephrasing or rewording of a passage where the same meaning remains intact does not constitute new matter.

The Examiner is considering certain limitations “new” in the phrases “‘wherein said’ vaccine composition, after a single administration, elicits protective immunity ‘in said porcine animal against said’ *Mycoplasma hyopneumoniae* infection ‘or disease for a duration of six months after the single administration.’” With the exception of the phrase “or disease,” this language was substantially copied from the proposed Examiner’s Amendment sent to the undersigned attorney by facsimile on August 22, 2005 (see attached true copy of the proposal) that showed the Examiner’s opinion of the allowable subject matter of the invention at the time. While the term “infection” was used by the Examiner and supported by the language of Claim 1 as filed, the phrase “or disease” was added to Applicants’ amendment to conform to the original “disease” terminology of method Claim 10 and the text on page 3, line 17 of the specification. Plus, the stated goal of the bacterin in the vaccine is to elicit protective immunity against disease or infection (see, for example, page 3, lines 26-28 of the application). It is certain that both terms have ample support in the application, as filed.

If the Examiner is complaining about the recitation of “said” with some terms, there is no reason for concern as all of these “said” terms have proper antecedent basis in the claim.

More to the point, the Examiner seems to believe that the previous amendment contained new matter by omitting a step from the method by not claiming an age limitation ("at the age of three weeks"). With all due respect, the Examiner's opinion is unjustified by the disclosure of the invention. In reading the specification, it is clear that Applicants have not omitted an important step from the claimed method. Indeed, the step is not taught as critical in the examples.

The unexpected results demonstrated in the working examples of the application show specifically that it is the adjuvant mixture comprising an acrylic acid polymer and a mixture of a metabolizable oil and a polyoxyethylene-polyoxypropylene block copolymer that provides the single dose immunity effect of the vaccine composition against infection or disease caused by *Mycoplasma hyopneumoniae*. The experiments showing that the vaccine composition elicited a long-term protective immunity from *Mycoplasma hyopneumoniae* after a single administration were set up to indicate that the immune response in the vaccinated pigs was due to the vaccine and not any environmental exposure (see page 11, lines 31-33).

Surprisingly, the new one-dose vaccination of the unique formulation of the present invention evidences superior, long-term immunity against *M. hyopneumoniae* infection to a full six months after the single dose administration, which is a significant improvement in activity over the two-dose vaccination schedule of Suvaxyn[®] RespiFend[®] MH (that did not contain the claim-recited mixture of metabolizable oil and a polyoxyethylene-polyoxypropylene block copolymer) and the four months duration of immunity of Ingelvac[®] M. hyo (that contains an Impran[®] water-in-oil emulsion and is effective through one dose but only lasts 120 days) (see Examples 3 and 4 on pages 12-25 of the specification). The side-by-side comparison, however, only tested the adjuvant systems to show that Applicants' unique adjuvant mixture was substantially superior to those taught in the art. There is no similar demonstration of any criticality in the timing of when the formulation of the invention must be administered to the pig. In other words, the teachings in the specification do not require an age limitation in the claimed method.

There is no question that the showing is relevant to the adjuvant system and has absolutely nothing to do with the age of the piglet. Since the pig's age is not crucial to the practice of the present invention, the age restriction is not warranted under the circumstances.

Practically speaking, the administration of the claim recited vaccine in the field will vary somewhat from an exact three weeks from date of birth; it is more a question of maturity than a precise age. For example, the dosing schedule will depend upon the maturity of the immune system and the depletion or weakening of the maternal antibodies present in the pig being immunized. Besides, the pig farmer may not know the precise age of all of the piglets on the farm or be able to immunize all piglets at the same age of three weeks. While the specification illustrates vaccinating the piglets at three weeks old and it is desirable to administer the vaccine to the piglets at an early age to avoid *Mycoplasma hyopneumoniae* infection or disease, the exact timing of the administration of the vaccine is not always at three weeks after birth. Vaccination protocol will follow what is customary in the usage and trade of the swine business. Most importantly, the ordinary practitioner will know when it is the right time and the right age to vaccinate the piglets to achieve successful results.

For all of the above reasons, Applicants believe that the age limitation "at three weeks of age" is not necessary in the pending claims. Applicants respectfully request that the new matter rejection be withdrawn and hope that the Examiner will permit the method claims to issue without age restriction.

The Examiner newly objects to Claim 17 under 37 C.F.R. § 1.75(c) as being in an improper form because a multiple dependent claim should refer to other claims in the alternative only. It is appreciated that the Examiner has brought this point to the undersigned attorney's attention, albeit after the final rejection. To promptly remedy the inadvertent mistake, Claim 17 has been amended in accord with the acceptable multiple dependent wording shown in M.P.E.P. § 608.01(n). Since the amendment directly addresses the Examiner's concern, it is respectfully asked that this after final amendment be entered and the objection be withdrawn.

If any outstanding issue remains in this case, the Examiner is invited to contact the undersigned attorney to discuss mutually agreeable solutions.

Accordingly, it is believed that this application is now in condition for an allowance.
Favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

Date: May 10, 2006

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Ms. Anne Rosenblum
518-475-1943**Examiner's Amendment**

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Anne Rosenblum in a telephonic interview on 22 August 2005.

This application has been amended as indicated below:

- (a) Claim 10 has been canceled.
- (b) New claim 19 has been added:

--Claim 19 (New). A method for protecting a porcine animal against *Mycoplasma hyopneumoniae* infection comprising: administering to said porcine animal at three weeks of age a vaccine composition by intramuscular, subcutaneous, oral or nasal route, wherein said vaccine composition, comprises an immunizing amount of a *Mycoplasma hyopneumoniae* bacterin, a pharmaceutically acceptable carrier, and an adjuvant mixture comprising a polyacrylic acid polymer and a mixture of metabolizable oil and a polyoxyethylene-polypropylene block copolymer, wherein said vaccine composition, after a single administration, elicits protective immunity in said porcine animal against said *Mycoplasma hyopneumoniae* infection for a duration of six months after the single administration--.

(c) In line 3 of claim 15, the limitation '(MHDCE/mL)' is replaced with the limitation --(MHDCE)/mL--.

(d) In line 2 of claim 15, the limitation 'CARBOPOL' is replaced with the limitation --a polymer of acrylic acid cross-linked with polyallylsucrose having the chemical formula $(\text{CH}_2\text{CHOOH})_n$ --.

(e) In line 1 of claim 17, the limitation 'claims 10-16' is replaced with --claims 10-12, 14 and 15--.

The amendment made to claim 15 via this Examiner's amendment has descriptive support at lines 27-29 on page 5 of the specification. New claim 19 finds descriptive support in the canceled claim 10; and the last paragraph on page 25 and lines 9-11 of page 21 of the instant specification.